CLAIMS

1. A process for the preparation of piroxicam:β-cyclodextrin inclusion compounds, comprising the following steps:

a) dissolving piroxicam and β-cyclodextrin in the presence of ammonium hydroxide in a suitable tank containing water at a temperature of at least 60°C;

b) bringing the solution to a temperature of at least about -10°C;

c) further lowering the temperature of the frozen solution to at least -20°C and preferably to between -30° and -40°C;

d) drying the frozen solution under vacuum.

2. A process as claimed in claim 1, characterized in that step b) is carried out by placing the solution on the temperature-controlled shelves of a freeze-dryer pre-cooled at at least–30°C.

3. A process according to claims 1-2, characterized in that step b) is carried at a rate equal to or higher than about 1°C/min.

4. A process as claimed in claim 1, characterized in that steps b) and c) are carried out by pouring the solution in a dewar filled with liquid nitrogen.

5. A process as claimed in claims 1-4, characterized in that step e) is carried out by bringing the temperature of the shelves at 50-60°C.

6. A process as claimed in claim 1 characterized in that the β-cyclodextrin to piroxicam molar ratio is comprised between 4:1 and 1:1.

7. A process according to claim 6 characterized in that the β-cyclodextrin to piroxicam molar ratio is 2.5:1

8. A 1:2.5 piroxicam:β-cyclodextrin inclusion compound obtained by the process of claims 1 to 5, characterized by the Raman spectrum of Figure 1.

9. Pharmaceutical compositions containing as active ingredient the inclusion compound of claim 8 in admixture with suitable excipients.

10. Pharmaceutical compositions as claimed in claim 9 in the form of tablets containing between 50 and 200 mg of said complex per unit dose.